Amendments to the Drawings

The Examiner has objected to the drawings because reference characters 18 and 82 have both been used to designate the part (piston and plunger) in Figure 13. The part has been renumbered to only be reference numeral 18 (piston). A replacement drawing is attached.

Attachment: Replacement Sheet
Annotated Marked-Up Drawing

REMARKS

Specification Objection

The Examiner has stated that incorporation of the article, "The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches" is ineffective because "subject matter that is not well known in the art can not be presented merely by incorporation by reference." The Examiner stated that the incorporation by reference will not be effective until correction is made to comply with 37 CFR 1.57(b), (c), or (d). Applicant believes that the incorporation by reference does comply with 37 C.F.R. 1.57(b) and (d).

For reasons discussed below with respect to the 112 rejection, the cited reference refers to nonessential material and may thus be incorporated by reference under 37 C.F.R 1.57(d).

Claim Objections

Claim 25 has been rejected by the Examiner as lacking sufficient antecedent basis for "the skin sensor." Claim 25 has been amended to correct this error.

112 Rejections

The Examiner has rejected claim 25 under 35 U.S.C. 112, first paragraph as failing to comply with the enablement requirement. The Examiner states that the disclosure related to the tailored stochastic sequence does not provide a method or description of how to create said series. The Examiner has also rejected claim 25 under 35 U.S.C. 112, second paragraph as being indefinite. The Examiner stated that the tailored stochastic sequence is not a defined characteristic of the invention. The Applicant has amended claim 25 to remove the "tailored" limitation. The claims now only refers to a stochastic sequence and not a tailored stochastic sequence.

Examiner has also stated that the incorporation by reference of the article "The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches," is improper and not sufficient for enablement. However, as noted below, applicant does not rely on that reference for enablement.

The use of stochastic sequences is well known. For example, see "Practical Identification of Functional Expansions of Nonlinear Systems Submitted to Non-Gaussian In puts" by Yves Goussard, William C. Krentz, Lawrence Stark, and Guy Demoment., Annals of Biomedical Engineering, Vol. 19, pp. 401-427, (1991), and also see "Measurement of the Weiner Kernels of a Non-linear System by Cross-correlation," Int. J. Contr. 2:237-254, (1965) (respectively, cited references 21 and 51 in "The Identification of Nonlinear Biological Systems: Volterra Kernel Approaches"). Both references are attached to the Supplemental Information Disclosure Statement being filed concurrently herewith.

Because the information is well known, further information is not needed for enablement. Claim 25, therefore complies with the enablement requirement as it is definite under 112.

102(b) Rejections

Claims 24 and 25 have been rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,354,273 to Hagen.

An embodiment of Applicant's device will be discussed without limitation of the claims. As shown in Applicant's Figure 13, there is shown a skin property sensor 200 associated with the drug delivery device 10. The sensor 200 can be integrated with the device 10, or it can be a separate unit. As shown, the sensor is positioned within the device 10, with the sensor tip 201 located near the orifice 14 of the injector.

Accordingly, when the device 10 is used with the sensor 200, the device 10 is initially placed against the skin, S, of the body such that the sensor tip 201 also rests against the skin. The controller 50 then drives the voice coil 202 to perturb the skin, while the force transducer 202 detects the force that the tip 201 applies to the skin, and the LVDT 208 detects the displacement of the skin.

The controller drives the source probe using a stochastic sequence. The data received from the sensor is fed back to the controller 50 which then evaluates the skin properties with the system identification techniques. Based on the detected skin properties, the controller 50 directs the actuator 28 to subsequently eject the drug, D, contained in the chamber 12, through the orifice 14 with the desired injection pressure.

Hagen describes a delivery apparatus for delivery of various media. As shown in Hagen's Figure 1, actuating power for the device is supported by the high pressure gas supply 30 to supply actuating gas under controlled pressure through a precision pressure regulator 34. The pressure of the actuating gas is controlled by a pressure setting control 26. The device also includes a compartment and piston apparatus 40, and actuating rod 52. The piston is further connected to the delivery apparatus 12 containing fluid 14. The pressure on the piston is regulated by comparing the actual pressure applied to the piston versus the pressure setting. The difference is the error and is reduced to zero to keep the pressure at the set level.

The device can have a pressure and/or temperature sensing element 27 to sense the pressure level of the medium being dispensed at the point where it is actually delivered for use, and/or to sense the skin temperature of the patient. The pressure setting can then be adjusted based on the pressure at the delivery point. The skin temperature of the patient can also be used as a parameter to sense if the pressure setting needs adjusting or shutting down (Col. 6, lines 58-68).

Hagen nowhere describes measuring displacement of the skin . Hagen's device only senses temperature and pressure of the medium being dispensed. Applicant measures displacement of the skin with applied force and then adjusts the injection pressure based on the displacement.

Independent claim 24 has been amended to recite measuring displacement of the skin with applied force. Hagen does not describe this limitation. Therefore, claim 24 and any claim dependent on the same is allowable for at least this reason.

Also, dependent claim 25 has been amended to recite a controller which drives a source probe that stimulates a local surface of the outer layer of the skin, the controller being coupled to a detector, and the controller driving the source probe using a stochastic sequence and determining a property of the outer layer using a measured response received from the detector. Hagen does not describe any of these limitations. Thus, dependent claim 25 is also allowable for this reason.

New independent claim 26 recites a skin property being measured, adjusting the injection pressure of the drug injector with a servo-controller based on the skin property, and subsequently injecting the drug into the body. In contrast, Hagen adjusts the pressure of the

injection based on the temperature of the skin and pressure of the medium at the injection point during the injection (Hagen, Abstract). Based on this distinction, new claim 26 is also allowable over Hagen.

Based on the preceding arguments, Applicant requests that the Examiner withdraw the rejection of all pending claims.

Supplemental Information Disclosure Statement

A Supplemental Information Disclosure Statement (SIDS) is being filed concurrently herewith. Entry of the SIDS is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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